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SOUTHERN SCHOOL OF PHARMACY  
*Department of Pharmaceutical Sciences*

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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In re U.S. Patent Application of:

Serial No.: 10/666,581

Yoshikazu Tobinaga et al.

Filed: September 18, 2003

Group Art Unit: 3763

Examiner: Aamer S. Ahmed

KENNEDY, COVINGTON  
LOBBE & HICKMAN

For: APPLICATOR FOR APPLYING FUNCTIONAL SUBSTANCES INTO  
HUMAN SKIN

Atlanta, Georgia February 8, 2006

## DECLARATION OF DR. AJAY K.BANGA

I, Dr. Ajay K. Banga, am a professor and the Chair of the Department of Pharmaceutical Sciences at Mercer University, Atlanta, Georgia.

I do hereby declare as follows:

1. A summary of my professional background is attached as Exhibit A.
2. I have had extensive experience in the field of transdermal delivery and microporation. My basis for making this patent declaration is my over 20 years of experience as an experimental scientist in the field of transdermal delivery, the last 14 (since obtaining my Ph.D. in pharmaceuticals at Rutgers – The State University of New Jersey), as an Assistant Professor and Associate Professor (tenured) at Auburn University in Alabama, and then as an Associate Professor and Professor at Mercer University in Atlanta, Georgia. I also serve as the Chairman of the Department of Pharmaceutical Science at Mercer University. In my career, I have had over fifty publications in leading refereed pharmaceutical journals, authored two single author books, which have been cited extensively by leading researchers in national and international literature. One of these books relates to transdermal delivery. In addition to this, I have contributed to over seventy-five (75) presentations at scientific meetings such as national meetings of the Controlled Release Society and the American Association of Pharmaceutical Scientists (AAPS). I have worked with skin microporation technology (thermal microporation) for the last 5 years with Altea Therapeutics and am very familiar with the literature and research groups working with microneedles. I serve on the Scientific Advisory Board of three companies and as a consultant to several companies. I have been invited to give lectures on transdermal delivery for numerous governmental, industrial, and academic institutions, both in the

United States and abroad, such as the Food and Drug Administration (FDA), the Georgia Institute of Technology, King's college London, Ciba Geigy Basel, and the Indian Institute of Technology in New Delhi. I was appointed the Editor-in-Chief for the journal *Critical Reviews in Therapeutic Drug Carrier Systems* in 2002 and am on the editorial advisory board of *PharmSci* (an AAPS electronic journal). I am a frequent reviewer on transdermal delivery and have published or preparing manuscripts for such prestigious journals as the *American Journal of Drug Delivery*, the *Journal of Controlled Release*, the *European Journal of Pharmaceutical Sciences*, the *International Journal of Pharmaceutics*, the *Journal of Pharmaceutical Sciences*, and *PharmSci*, a journal of the AAPS. I have received several grants/contracts in the area of transdermal delivery. I also review research proposals for grant committees, including the National Institutes of Health (NIH). Please see my attached CV for a more complete summary of my credentials (Exhibit A).

3. In preparation for making this Declaration, I have reviewed a copy of U.S. Patent Application No. 10/666,581 as originally filed; a copy of an Amendment and Response filed September 15, 2005 in the application; a copy of an Office Action dated November 2, 2005, issued by the U.S. Patent and Trademark Office in that application; a copy of Park et al. U.S. Patent Application Publication No. U.S. 2002/0082543 A1; a copy of D'Ussel U.S. Patent Application Publication No. U.S. 2004/0010237 A1

4. I have studied Claim 1 as it appears in the Amendment and Response of September 15, 2005, and compared it in detail with the subject matter of the Park and D'Ussel Patent Publications, and I have also considered the reasons stated in the Office Action of November 2, 2005, for rejecting Claim 1 as being obvious based on the combination of the Park and D'Ussel Publications.

5. Claim 1 as set out in the Amendment and Response of September 15, 2005, reads as follows:

Claim 1. An applicator for applying functional substances into human skin, comprising:

- (a) a base,
- (b) a plurality of microneedles fixed to said base and projecting therefrom a distance sufficient to penetrate into the skin, said microneedles being made of a material that is substantially sugars that dissolve within the human body and capable of disintegration and dispersion into the skin, and
- (c) a functional substance carried by said microneedles for delivery by said microneedles into the skin.

6. Having microneedles made of a material that is substantially sugar that dissolves within the human body and are capable of disintegration and dispersion into the skin is a unique feature having the advantage, unexpected, with other microneedles, of delivering functional substances into the skin with the disintegration and dispersion resulting in dissemination of the functional substances without requiring any further physical act to separate the functional substances from the microneedles into the skin.

7. This feature of microneedles made substantially of sugar that dissolves within the human body and disintegrates and disperses into the skin for depositing of functional substances into the skin is not disclosed or suggested or obvious from the teachings of the Park and D'Ussel patents.

8. The Park patent does not teach or suggest microneedles made of sugar material. Rather, the Park patent teaches the use of polymers, metals, ceramics, semi-conductor materials and composites. Polymer needles made of biodegradable polymers such as PLGA will release drug very slowly over a period of time to provide sustained drug delivery. This would be a very different application as compared to the present invention where sugar microneedles can quickly dissolve in the skin to provide instant (bolus) drug delivery. Using just a sugar tip from a conventional needle and extrapolating that information to make an all-sugar microneedle will not be obvious to somebody skilled in this art, and also the manufacturing methods will be entirely different.

9. The D'Ussel patent discloses metal, not sugar, microneedles with only a pointed tip of sugar that serves as a seal for temporarily retaining injection liquids in the needles. The tips are formed by vertically immersing the needles in a hot solution of material, which may be sugar, and then raising the needles so that a sharp point is formed. There is no way that an entire microneedle can be formed in this manner as there must be a substantial portion of the microneedle formed of metal or rigid material on the end of which a drop of sugar can be formed to provide a sharp tip. Dipping a flat base or only partially formed microneedles in a hot bath and removing them would not conceivably result in a needlelike formation.

10. In addition, D'Ussel teaches sterilization of the needles, which would destroy any sugar formulation.

11. The D'Ussel patent does not teach or suggest the use of microneedles and particularly the use of sugar tips on microneedles. Rather, D'Ussel teaches applying tips to conventional needles. There is no known technique for dipping microneedles into a hot sugar solution and having tips formed on the microneedles when the microneedles are removed from the bath. Also, microneedles are very different from conventional needles. The former is a very recent innovative approach to drug delivery while the latter has been used for a very long time.

12. For the foregoing reasons, it is my firm opinion that the subject matter of Claim 1 of U.S. Patent Application No. 10/666,581 would not have been obvious to someone ordinarily skilled in the art from the teachings or suggestions of the Park and D'Ussel patents.

13. Claim 33 of U.S. Patent Applications 10/666,581, as appears in the Amendment and Response, dated September 15, 2005, reads as follows:

Claim 33. An applicator for applying functional substances into human skin, comprising:

(a) a base,

(b) a plurality of microneedles fixed to said base and projecting therefrom a distance sufficient to penetrate into the skin, said microneedles being made of a material that is capable of disintegration and

dispersion into the skin,

(c) a functional substance carried by said microneedles for delivery by said microneedles into the skin, and

(d) said microneedles having relatively thick inner portions and relatively thick outer portions with constricted intermediate portions therebetween to facilitate separation of said outer portions from said inner portions with the outer portions remaining in the skin.

14. Claim 33 features a microneedle construction where there are relatively thick inner and outer portions with constricted intermediate portions, with the intermediate portions facilitating separation of the outer portions from inner portions so that the outer portions will break off and be retained in the skin. As the microneedles are of a material that is capable of disintegration and dispersion into the skin, the outer portions will be dissipated into the skin without any lasting harm. Further, the outer portions can contain the functional substance that is to be dispersed into the skin, which can occur effectively as the outer portions that have been left in the skin disintegrate.

15. There is no teaching or suggestion in the Park and D'Ussel patent applications of this restricted intermediate portion between outer and inner portions that facilitate breaking off of the outer portion. Rather, the Park and D'Ussel patents disclose and suggest nothing other than conventional needles that taper generally from a larger base to a smaller tip.

16. Therefore, it is my opinion that the subject matter of Claim 33 of U.S. Patent Application No. 10/666,581 would not be obvious to one ordinarily skilled in the art from the Park and D'Ussel patents.

17. Claim 34 of U.S. Patent Application Serial No. 10/666,581 as presented in the Amendment and Response of September 15, 2005, reads as follows:

Claim 34. An applicator for applying functional substances into human skin, comprising:

(a) a base,

(b) a plurality of microneedles fixed to said base and projecting therefrom a distance sufficient to penetrate into the skin, said microneedles being made of a material that is capable of disintegration and dispersion into the skin, and

(c) microcontainers containing said functional substance, said microcontainers being contained within said microneedles for delivery into the skin.

18. The significant feature of Claim 34 is the inclusion of microcontainers containing functional substances with the microcontainers being contained within microneedles for delivery into the skin upon disintegration and dispersion of the microneedles.

19. This feature is not disclosed or suggested in either the Park or D'Ussel patents or any obvious combination thereof

20. The Office Action of November 2, 2005, refers to the disclosure of Figure 3 of Park as disclosing this feature. However, Figure 3 of the Park patent publication has nothing to do with microcontainers. It discloses different layers of material, none of which are microcontainers. These layers extend completely across the microneedles and do not provide any interior container. There is no microcontainer disclosed or suggested in the D'Ussel patent publication.

21. Therefore, it is my opinion that the subject matter of Claim 34 of U.S. Patent Application Serial No. 10/666,581 would not be obvious from any combination of the Park and D'Ussel patent publications.

I further declare that statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful, false statements and the like are punishable by fine or imprisonment, or both under § 1001 of Title 18 of the United States Code, and such willful false statements may jeopardize the validity of any patents issued from the patent application.

February 8, 2006

A handwritten signature in black ink, appearing to read "Ajay K. Banga". The signature is stylized with a large, circular initial "A" and a long, sweeping underline.

Ajay K. Banga, Ph.D.  
Professor & Chair

## Exhibit A

### CURRICULUM VITA

**Ajay K. Banga**

Professor and Chairman  
Dept. Pharmaceutical Sciences, School of Pharmacy  
Mercer University, 3001 Mercer Univ Drive  
Atlanta, GA 30341-4155

Tel.(678) 547-6243  
Fax (678) 547-6423; E-mail: *banga\_ak@mercer.edu*

### EDUCATION

Doctor of Philosophy (May 1990), Rutgers University, NJ.

Master of Science in Pharmaceutics (Dec. 1986), University of Oklahoma, Oklahoma City, OK.

Masters degree in Pharmaceutics (May 1983), University of Delhi, New Delhi, India.

Bachelors degree in Pharmacy (May 1981), University of Delhi, New Delhi, India

### POSITIONS HELD/CHRONOLOGICAL VITA

7/04 - Present	<i>Chairman, Dept Pharm Sci, Mercer University, Atlanta, GA</i>
7/03 - Present	<i>Professor, Mercer University, Atlanta, GA</i>
3/99 - 6/03	<i>Associate Professor, Mercer University, Atlanta, GA (Tenured effective 7/01)</i>
9/96 - 2/99	<i>Associate Professor with Tenure, Auburn University, AL</i>
8/91 - 9/96	<i>Assistant Professor, Auburn University, AL</i>
5/90 - 8/91	<i>Formulation Scientist at Bausch &amp; Lomb, Rochester, NY.</i>
8/86 - 5/90	<i>Ph.D Research at Controlled Drug-Delivery Research Center, Department of Pharmaceutics, College of Pharmacy, Rutgers - The State University of New Jersey, New Jersey. Also, served as graduate teaching assistant (1986-87) and as graduate fellow (1987-90).</i>
8/85 - 8/86	<i>M.S. Research at Pharmaceutics Division, School of Pharmacy, University of Oklahoma, Oklahoma City, OK. Also, was graduate teaching assist.</i>
5/83 - 8/85	<i>Research Scientist at Ranbaxy Labs Ltd., N.Delhi, India</i>
5/81 - 5/83	<i>Masters Research in pharmaceutics at Univ. of Delhi, New Delhi, India.</i>
5/77 - 5/8	<i>Bachelors degree in pharmacy, Delhi Institute of Pharmaceutical Sciences Research, Univ. of Delhi, N.Delhi, India.</i>

## HONORS/PROFESSIONAL

Distinguished Educator Award, School of Pharmacy, Mercer University, Atlanta, GA, presented at the commencement on May 7, 2005.

Received Gateway Research Scholarship from American Foundation for Pharmaceutical Research (AFPE) as faculty advisor for participating student, Adina C. Hirsch., for 2003-04.

Research Award, School of Pharmacy, Mercer University, Atlanta, GA, presented at the commencement on May 5, 2001.

### Scientific Advisory Boards

Altea Therapeutics, Atlanta, GA, USA  
 Transport Pharmaceuticals, Framingham, MA, USA  
 DiTeba Research Laboratories, ON, Canada

### Editorship/Editorial Boards

Editor-in-Chief, Critical Reviews in Therapeutic Drug Carrier Systems 1/02 - present

#### *Editorial advisory boards:*

PharmSci (an AAPS electronic journal)

1/99 - present

Critical Reviews in Therapeutic Drug Carrier Systems

1/98 - 12/01

### *Other Honors*

Invited to serve on the following Special Emphasis Panels in Bethesda/Washington area as a reviewer for grants submitted to the National Institutes of Health:

- Center for Scientific Review (CSR), Drug Delivery ZRG 1 SSS-2 (50) Study Section, R01/R21 grants 7/03
- CSR, Hematopoiesis Study section, SBIR/STTR grants, 7/03
- NIH/NIAID program grant applications on control strategies in infectious diseases, 8/02.
- Vaccine study panel to review NIH/NIAID SBIR/STTR/R01 grant applications, 7/01.
- NIH/NIAID grant applications, "Research on Topical Microbicides for the prevention of STDs/HIV", 5/99

Paper presented at the following meetings won the best presentation/poster awards:

- A. Badkar and A. Banga, Effects of formulation pH and buffers on thermal properties and conformational stability of Immunoglobulin G, 24<sup>th</sup> annual meeting of the Graduate Research Association of Students in Pharmacy (GRASP), Mercer University, Atlanta, GA, June 4-6, 2004 (best podium award).
- P. Pendse, R. Bright, R. Durland, C. Wang, and A.K. Banga, Thermal microporation as a novel technique for transdermal immunization with model antigens 24<sup>th</sup> annual meeting of the Graduate Research Association of Students in Pharmacy (GRASP), Mercer University, Atlanta, GA, June 4-6, 2004 (one of the best poster award).
- D.P. Joshi, A. Chaturvedula, S.L. Chang, S.E. Mills, A.M. Smith, and A. K. Banga, Steady infusion of insulin via micropores through the stratum corneum in hairless rats, 24th Annual meeting of the Southeastern pharmacology society, Mercer University, Atlanta, GA, October 16-18, 2003 (third place award for best student podium).
- A. Chaturvedula, R. Conjeevaram, C. Anderson, R. Morris, and A. Banga, Transdermal delivery of propranolol HCl to hairless rats using a self-contained iontophoretic patch, presented at the annual meeting of graduate research association of students in pharmaceuticals conference, Richmond, VA, May 30-June 1, 2003 (Best poster award).
- A. Badkar, P. Yohannes, and A.K. Banga, Thermal characterization of protein formulation using modulated temperature differential scanning calorimetry, best presentation award in the Biomedical Sciences at the annual meeting of the Georgia Academy of Sciences, March 21-22, 2003.
- Rajkumar Conjeevaram and Ajay K. Banga, Transdermal iontophoretic delivery of timolol, presented at the 20th Annual Meeting of GRASP, June 2-4, 2000, University of Maryland, Baltimore, Maryland (best poster award).
- Kishore Talluri, Advait Badkar, Srinu Tenjarla, and Ajay K. Banga, In Vitro release testing on a peptide gel as per SUPAC-SS recommendations, presented at the *19th Annual Meeting of GRASP, Holiday Inn, Columbia, SC, May 28-30, 1999* (best poster award).
- Manohar Katakam, Leonard N. Bell, and Ajay K. Banga, Role of nonionic surfactants on the stability of recombinant human growth hormone, presented at the *15th Annual Meeting of GRASP, St. John's University, Jamaica, NY, June 2-4, 1995* (best poster award).

Interviewed (7/99) by "patient care" magazine as an expert/consultant for an article on "drug delivery" (published Jan.2000) intended for physicians - the magazine has a circulation of 125,000 and is targeted to family physicians and general internists nationwide.

Invited (4/97) on the International panel of evaluators for Current Drugs Ltd., a London based company providing expert information on drugs under research and development. Submitted several meeting reports for them.

Graduate student research award to my Ph.D. student, Ms Shu-Lun Chang, for the project, *Transdermal iontophoretic delivery of calcitonin*. Auburn University, AL.

Elected as a full member to Rho Chi and Sigma Xi. Selected for inclusion in Marquis Who's Who in Science and Engineering, 3rd Ed., in press; also in Marquis Who's Who in the South and Southwest, Silver 25th Ed., 1997-98, and 26th Ed (in press) and in Dictionary of International Biography, 26th Ed., 1998 (in press).



Media coverage of research activities in Business Georgia magazine (2003/2004), Georgia Trend (2003), and Auburn University Fall 92 Research Update Newsletter and Fall 92 Extension Update Newsletter, and in newspapers in Montgomery, Mobile and Birmingham, Alabama.

Awarded medal by Indian Pharmaceutical Association for First rank in the College of pharmacy, both for bachelors and masters degree in pharmacy, overall and for individual years. Also, secured first rank in pre-medicine year at Hans Raj College, University of Delhi. Served on the executive council of the Indian pharmaceutical association as university representative and on the editorial board of college magazine.

## **RESEARCH GRANTS/CONTRACTS FUNDED/OTHER FUNDING**

*Principal and only investigator on the grants unless otherwise specified*

Delivery of methotrexate into skin by microneedles, Transport Pharmaceuticals, \$ 61,800, November 1, 2005 to October 31, 2007.

Enhancement methods for transdermal delivery of proteins, Pfizer Inc. (New York, NY), \$ 150,000, October 15, 2005 to October 14, 2006.

Delivery of sumatriptan succinate by iontophoresis, Travanti Pharma (Oakdale, MN), \$ 35,400, September 1, 2005 to August 31, 2006.

Evaluation of drugs for iontophoretic delivery to control acne and psoriasis, Transport Pharmaceuticals (Framingham, MA), \$ 100,800, April 18, 2005 to April 17, 2007.

Screening of therapeutic chemical/biological entities for transdermal and/or iontophoretic delivery, Solvay Pharmaceuticals B.V., the Netherlands, \$ 199,200, Jan.1, 2005 to Dec.31, 2006.

Evaluation of drug formulations for transdermal delivery, Undisclosed client, \$ 64,800, Jan.1, 2005 to Dec.31, 2005.

Evaluation of acyclovir formulations in iontophoretic drug cartridges, Transport Pharmaceuticals (Framingham, MA), \$ 21,000, Jan.1, 2005 to Dec.31, 2005.

Transdermal delivery of small molecules by thermal microporation, Altea Therapeutics (Atlanta, GA), \$ 183,600, Jan. 1, 2005 to Dec. 31, 2006.

Transdermal delivery of proteins and peptides by thermal microporation, Altea Therapeutics (Atlanta, GA), \$ 112,800, Jan. 1, 2005 to Dec. 31, 2006.

Delivery of NSAIDs into skin by iontophoresis and sampling by microdialysis, Travanti Pharma, Oakdale, MN, \$ 25,200, October 18, 2004 to October 17, 2006.

Transdermal delivery of nicotine and its salts - issues and innovations, GlaxoSmithKline (Parsippany, NJ), \$ 93,000, July 1, 2004 to June 30, 2005.

Delivery of proteins and peptides through the skin by the Altea Therapeutics PassPort System in animal models, Altea Therapeutics (Atlanta, GA), \$ 127,200, Jan. 1, 2004 to Dec. 31, 2004.

Delivery of small molecule drugs through the skin by the Altea Therapeutics PassPort System in animal models, Altea Therapeutics (Atlanta, GA), \$ 97,200, Jan. 1, 2004 to Dec. 31, 2004.

Iontophoretic transdermal delivery of nicotine salts, GlaxoSmithKline (Parsippany, NJ), \$ 24,000, October 1, 2003 to March 31, 2004.

Skin permeation of nicotine, GlaxoSmithKline (Parsippany, NJ), \$ 24,000, August 15, 2003 to February 14, 2004.

Delivery of parathyroid hormone through microporated skin, Altea Therapeutics (Atlanta, GA), \$ 48,000, April 1, 2003 to March 31, 2004.

Modulated drug delivery through skin by iontophoresis and sampling by microdialysis, Birch Point Medical Inc., Oakdale, MN, \$ 15,600, May 15, 2003 to May 14, 2004.

In vivo transdermal delivery of tetrahydrocannabinol formulations, Murty Pharmaceuticals, Inc., \$ 8,400. Jan. 30, 2003 to Jan. 9, 2005.

Skin permeation studies of drug formulations, Solvay Pharmaceuticals, Inc., Marietta, GA, \$ 26,400, Jan 2, 2003 to June 30, 2003.

Modulated transdermal drug delivery by iontophoresis, Birch Point Medical Inc., Oakdale, MN, \$ 20,160, April 15, 2002 to April 14, 2003.

Drug solubilization by lipid vehicles, Lipocine Inc., Salt Lake City, UT, \$ 5040, March 1, 2002 to August 30, 2002.

Enhanced insulin delivery by microporation and other active energy based flux enhancement, Altea Development Corporation, Atlanta, GA, \$ 20,400, Jan.21, 2002 to Jan.20, 2003.

Enhanced in vivo transdermal drug delivery by iontophoresis, Birch Point Medical Inc., Oakdale, MN, \$ 10,080, Jan.1, 2002 to Dec.31, 2002.

Enhanced *in vivo* transdermal drug delivery by microporation and other active energy based flux enhancement, Altea Development Corporation, Atlanta, GA, \$ 178,680, July 1, 2001 to June 30, 2003.

Enhanced *in vitro* transdermal drug delivery by microporation and other active energy based flux enhancement, Altea Development Corporation, Atlanta, GA, \$ 112,800, Jan.18, 2001 to Jan.17, 2003.

Transdermal delivery of tetrahydro-cannabinol, Murty Pharmaceuticals, Lexington, KY, \$ 8,400. Dec.15, 2000 to Dec.15, 2002.

Delivery of pDNA and protein antigens through microporated skin, Altea Development Corp., Atlanta, GA, \$ 228,420, November 1, 2000 to October 30, 2002. Principal Investigator. (Co-investigators: Drs Holbrook and Rothenberg).

Electrically modulated skin delivery of beta-blockers, National Institutes of Health, \$ 140,002, August 1, 2000 to July 31, 2003.

Delivery of insulin through microporated skin, Altea Development Corp. (Atlanta, GA), \$ 20,400, Aug. 10, 2000 to Aug.9, 2001.

Drug diffusion through Eudragit Films as a function of film composition, Elan Corporation (Gainesville, GA), \$ 5040, 8/1/00-11/30/00. Formulation and delivery of interferon, Altea Development Corp. (Atlanta, GA), \$ 20,400, July 5, 2000 to Jan.4, 2001.

Formulation of a plasticized gel for burn applications, Demegen, Inc. (Pittsburgh, PA), \$ 20,400, Jan.15, 2000 to Jan.15, 2001.

Skin permeation studies for ibuprofen and flutamide, Aviana Biopharm (Wynnewood, PA), \$ 4080, Jan.15, 2000 to Jan.15, 2001.

Electrically assisted delivery of fentanyl, Genetronics, Inc. (San Diego, CA), \$ 4080, May'99 to Aug'99.

Electrically assisted delivery of parathyroid hormone, Genetronics, Inc. (San Diego, CA), \$ 5040, March'99 to December'99.

Preparation and evaluation of a vaginal peptide gel, Demegen, Inc. (Pittsburgh, PA), \$ 8,400, March' 99 to Feb' 2000.

Claim support study of salicylic acid body wash formulas, Blistex, Inc. (Oak Brook, IL), \$ 8400. April'99 to July'99. Received another \$ 2400 in May'99 to expand the project with more human subjects.

Electrically enhanced transdermal delivery of calcitonin, Small business innovation research grant, National Institute of Health thru Genetronics, Inc. (San Diego, CA), Aug' 97, \$ 89,572 (direct costs). Author of grant, investigator for subcontract work and consultant.

Investigation of potential vaginal uptake of an anti-infective peptide, Demeter Biotechnologies, Ltd, Durham, NC, \$ 15,000. January 1998 to August 1998.

Electroincorporation of buprenorphine microspheres in skin for treatment of opiate addiction, Genetronics Inc., San Diego, CA. \$ 5,000. August 1997 to April 1998.

Gel formulation of nitroglycerin and transdermal delivery, \$ 5,000. Seatrache Pharmaceuticals, Gadsden, AL.

Electrically-enhanced transdermal delivery of macromolecules, \$ 3,800. School of Pharmacy Competitive Grant-in-Aid, March' 97.

Mechanism of release of potassium chloride from ethylcellulose and composite films, \$ 10,000. Eurand America, Inc., a division of American Home Products, Dayton, Ohio. February' 97.

Electrically assisted transdermal delivery of colchicine from liposome formulations, Genetronics Inc., San Diego, CA. \$ 2,200. February 1997. Electrically enhanced transdermal drug delivery of calcitonin, Genetronics Inc., San Diego, CA, \$ 8,000. September 1996- March 1997.

Controlled release parenteral delivery system of buprenorphine, Small business innovation research award granted to Murty Pharmaceuticals, Inc by the National Institute of Health. \$ 98,754. One of the Investigators in sub-contract work.

Electrically assisted transdermal drug delivery of prostaglandin E1, Genetronics Inc., San Diego, CA, \$ 8,650. March 1996 to March 1997.

Electroincorporation of insulin microspheres in human skin, Genetronics Inc., San Diego, CA, \$ 5,000. October 1995.

Emdex as a stabilizing excipient to prevent aggregation of peptide/protein drugs Mendell Drug Co., \$ 20,000.

Electrically assisted delivery of Vasopressin through human skin, Auburn University Competitive Research Grant-in-Aid. Proposal was ranked #1 for funding on a university wide competitive basis. \$ 10,000.

Use of Emu oil as a transdermal penetration enhancer, American Emu Association. \$8,000 Co-Principal Investigator.

To investigate the role of excipients to prevent or minimize the aggregation of human growth hormone", School of Pharmacy Competitive Grant-in-aid. \$ 3,500.

"Optimization of experimental conditions during transdermal iontophoresis studies, School of Pharmacy Competitive Grant-in-aid. \$ 3,600.

Gift of chromatographic equipment from Lederle, a division of American Cyanamid Company, NY. The 12 pieces of used equipment gifted were valued by department (Pharmaceutical Sciences, Auburn University) at \$ 40,000. Gift of human skin (\$6000) and iontophoresis units (\$ 1950) from Novartis Pharmaceuticals and HPLC analytical instrument (\$ 15,000) from Bertek Labs to our laboratory at Mercer University.

## **BOOKS, PUBLICATIONS, AND PRESENTATIONS:**

**Books** (both books are single author and not edited volumes)

*Therapeutic Peptides and Proteins: Formulation, Processing, and Delivery Systems*, Ajay K. Banga, Second Edition, 376pp., CRC Press/Taylor & Francis, 2005.

*Electrically-assisted transdermal and topical drug delivery*, Taylor & Francis, London, 1998.

**Publications** (\*Corresponding author)

Application of Tzero calibrated modulated temperature differential scanning calorimetry to characterize model protein formulations, A. Badkar, P. Yohannes, and A. Banga, *International Journal of Pharmaceutics*, in press.

Iontophoretic Topical and Transdermal drug delivery, A. Banga, *Drug Delivery Companies Report*, Autumn/Winter 2005, PharmaVentures, UK.

Dermal, subdermal, and systemic concentrations of granisetron by iontophoretic delivery, A. Chaturvedula, D. P. Joshi, C. Anderson, R. Morris, W.L. Sembrowich, and A.K. Banga, *Pharmaceutical Research*, 22 (2005) 1313-1319.

*In vivo* iontophoretic delivery and pharmacokinetics of salmon calcitonin, A. Chaturvedula, D. P. Joshi, C. Anderson, R. Morris, W.L. Sembrowich, and A.K. Banga, *Int. J. Pharm.*, 297 (2005) 190-196.

Factorial design approach to evaluate interactions between electrically assisted enhancement and skin stripping for delivery of tacrine, A. C. Hirsch, R.S. Upasani, and A.K. Banga, *J.Control.Rel.*, 103 (1) (2005) 113-121.

Response surface methodology to investigate the iontophoretic delivery of tacrine hydrochloride, R.S. Upasani and A.K. Banga, *Pharmaceutical Research*, 21(12) (2004) 2293-2299.

Assessment of group projects beyond cooperative group effort, Ajay K. Banga, *Journal of Pharmacy Teaching*, 11(2) (2004): 115-123.

Iontophoretic *in vivo* transdermal delivery of beta-blockers in hairless rats and reduced skin irritation by liposomal formulation, R. Conjeevaram, A. Chaturvedula, G.V. Betageri, G. Sunkara, and A.K. Banga\*, *Pharmaceutical Research*, 20 (9) (2003) 1496-1501.

Delivery of Protein Therapeutics, Ajay K. Banga, in: World Markets Series Business Briefing, Pharma Tech 2003, p.198-202.

Stability of a transdermal salmon calcitonin formulation, S.Chang, G.A. Hofmann, L. Zhang, L.J. Deftos, and A.K. Banga\*, *Drug Delivery*, 10 (2003) 41-45.

Electrically modulated transdermal delivery of fentanyl, R. Conjeevaram, A.K. Banga\*, and L. Zhang, *Pharm.Res.*, 19 (2002) 440-444.

Electrically enhanced transdermal delivery of a macromolecule, A.V. Badkar and A.K. Banga, *J. Pharm. Pharmacol.*, 54 (2002) 907-912.

Drug delivery today, Ajay K. Banga, in: World Markets Series Business Briefing, Pharma Tech 2002, World Markets Research Centre Ltd., p.150-154.

Electrically assisted transdermal delivery of buprenorphine, Sagarika Bose, William R. Ravis, Yuh-Jing Lin, Lei Zhang, Gunter A. Hofmann, and Ajay K. Banga\*, *J.Cont.Rel.*, 73 (2001) 197-203.

Transdermal iontophoretic drug delivery, Ajay K. Banga, in: World Markets Series Business Briefing, Pharma Tech 2001, World Markets Research Centre Ltd., p.203-204.

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R. Upasani, Y. Yang, and A. Banga, Mapping the influence of ionization state of nicotine and ionic surfactants on the iontophoretic transport of nicotine using response surfaces, presented at the 32<sup>nd</sup> annual meeting of the Controlled release society, June 18-22, 2005, Miami Beach, FL.

G. Tolia, S. Chang, H. Branam, S. Mills, S. Desai, C. Kolli, and A. Banga, Transdermal delivery of hydromorphone in hairless rats by thermal microporation, presented at the 32<sup>nd</sup> annual meeting of the Controlled release society, June 18-22, 2005, Miami Beach, FL.

S. Late and A. Banga, Differential scanning calorimetry as a screening technique to assess the compatibility of granisetron hydrochloride with commonly used tablet excipients, 25<sup>th</sup> annual meeting of the Graduate Research Association of Students in Pharmacy (GRASP), Long Island University, NY, June 10-12, 2005.

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Narendra B. Vutla, Guru V. Betageri, and Ajay K. Banga, Encapsulation of Leucine Enkephalin in multilamellar and large unilamellar liposomes, *15th Annual Meeting of GRASP, St. John's University, Jamaica, NY, June 2-4, 1995.*

Transdermal iontophoretic delivery and degradation of vasopressin across human cadaver skin, Ajay K. Banga, Manohar Katakam and Ruchira Mitra, *AAPS Annual Meeting, San Diego, November 6-10, 1994.*

Aggregation of Insulin and its prevention by carbohydrate excipients, Manohar Katakam and Ajay K. Banga, *AAPS Annual Meeting, San Diego, November 6-10, 1994.*

Transdermal iontophoretic delivery of peptide/protein drugs, Ajay K. Banga and Ruchira Mitra, *71st annual meeting of the Alabama Academy of Sciences, Troy State University, Troy, AL, March 24, 1994*

Aggregation of proteins and its prevention by carbohydrate excipients, Manohar Katakam and Ajay K. Banga, *71st annual meeting of the Alabama Academy of Sciences, Troy State University, Troy, AL, March 24, 1994*

Transdermal iontophoretic transport of an aromatic amino acid and the effect of cyclodextrins on such transport, Ajay K. Banga, Daniel L. Parsons and Manohar Katakam, *AAPS Annual Meeting, Orlando, Nov. 1993.*

Aggregation of albumins and gamma globulin in the solid state and its prevention by excipients, Manohar Katakam and Ajay K. Banga, *AAPS Annual Meeting, Orlando, Nov. 1993.*

Insulin aggregation and its prevention by cyclodextrins, Ajay K. Banga and Ruchira Mitra, *AAPS Annual Meeting, San Antonio, Nov. 15-19, 1992.*

Hydrogels for iontophoretic delivery of peptide drugs, Ajay K. Banga and Yie W. Chien, *World Technology Exchange meeting, Bausch & Lomb, Rochester, NY, 1991.*

Transdermal iontophoretic delivery of peptide drugs: delivery mechanisms and hydrogel formulations, Ajay K. Banga and Yie W. Chien, *AAPS Annual meeting, Las Vegas, Nevada, Nov. 4-8, 1990.*

Iontophoretic transdermal delivery of insulin: I. Characterization of in-vitro permeation profiles, Ajay K. Banga and Yie W. Chien, *AAPS Annual Meeting, Atlanta, Georgia, Oct. 22-26, 1989.*

Iontophoretic transdermal delivery of insulin: II. Factors influencing in-vitro profiles, Ajay K. Banga and Yie W. Chien, *AAPS Annual Meeting, Atlanta, Georgia, Oct. 22-26, 1989.*

The incorporation of simethicone into clear base liquid orals, Ajay K. Banga, Loyd V. Allen et al., *Joint Japan-United States Congress of Pharmaceutical Sciences, Honolulu, Hawaii, Dec.2-7, 1987.*

## **INDUSTRIAL EXPERIENCE**

*Formulation Scientist* at Bausch & Lomb, Rochester, NY. Responsible for formulation development and pilot plant scale up for sterile dosage forms. Manufactured several pilot batches and clinical supplies under GMP conditions. Started a new formulation laboratory, including sourcing and purchase of laboratory instrumentation.

*Research Scientist* at Ranbaxy Labs Ltd, the largest pharmaceutical company in India, and with business extending to more than 50 countries worldwide, including collaboration with Bausch & Lomb and a major global alliance with Eli Lilly and Company. Responsibilities included research on controlled release dosage forms and formulation development in conventional solid (tablets, capsules and dry syrups) and liquid (syrups and suspensions) dosage forms. Worked on preformulation studies, product development bench work, stability studies, pilot plant scale up and technology transfer to production floor.

## **INVITED LECTURES/WORKSHOPS CONDUCTED**

Formulation and delivery of peptide/protein drugs, invited lecture at National Institute of Technology and Management, Lucknow, India and Matrix Laboratories, Hyderabad, India, December 2005.

Enhancement technologies for transdermal delivery, invited lecture at the Food and Drug Administration, June 2, 2005, Silver Springs, MD.

Enhancement methods for transdermal drug delivery, invited lecture at Georgia Institute of Technology, Atlanta, GA, April 26, 2005.

Coordinated a discussion on "Education in Pharmaceutical Sciences" at the Georgia Institute of Technology, Atlanta, GA, April 26, 2005.

Formulation of protein drugs and Enhanced transdermal delivery, lectures (total 6 hrs) in drug delivery graduate course at School of Pharmacy, Florida A&M University, Tallahassee, FL, April 5, 2004.

Transdermal drug delivery: Present & future directions, invited CE lecture, Mercer University, Atlanta, GA, Nov.11, 2003.

Protein formulation and delivery, invited lecture at Altea Therapeutics, Atlanta, GA, Nov.22, 2002.

Approaches to enhanced/modulated drug delivery through skin, invited lecture at Solvay Pharmaceuticals, Marietta, GA, June 13, 2002.

Transdermal modulated drug delivery, presentation to the Deans Board of Visitors, Mercer University School of Pharmacy, May 15, 2002.

Skin Delivery of Macromolecules, invited lecture at the 53<sup>rd</sup> Indian Pharmaceutical Congress and the Center for Biomedical Engineering at the Indian Institute of Technology in New Delhi, Dec.20-23, 2001.

Transdermal delivery of macromolecules, invited lecture at the Seminar program of University of Georgia College of Pharmacy, Athens, GA, Jan. 11, 2001.

Delivery systems and formulation considerations for peptide/protein drugs, a full-day lecture in a drug delivery graduate course at Florida A & M University, Tallahassee, Florida, May 3, 2000.

Organized a short course on "Protein and Gene-based Drugs: Product Development and Delivery Challenges" at the 1999 annual meeting of the American Association of Pharmaceutical Scientists, November 14-18, 1999, New Orleans, LA. Also, gave the opening lecture at this course, "Challenges in the product development and delivery of protein-based drugs."

Electrically-assisted transdermal delivery of peptides, invited lecture at the 19th Annual Meeting of GRASP (Grad. Res. Assoc. Students Pharmaceutics), Holiday Inn, Columbia, SC, May 29-30, 1999.

Electrically assisted transdermal and topical drug delivery, presentation to the seminar program at the School of Medicine, University of Alabama at Birmingham, AL, February 3, 1999.

Applications of physics in the design of novel drug delivery systems, lecture to undergraduate physics class, Auburn University, AL, January 15, 1999.

Organized (as one of the speakers) a 2-day, 3-speaker seminar on "Product Development of Therapeutic Peptides and Proteins", Logan Airport Ramada, Boston, MA, June 11-12, 1998.

Formulation of antimicrobial peptides as gels for Vaginal Use, presentation at Pre-Clinical Topical Microbicides Workshop, National Institute of Allergy and Infectious Diseases, Embassy Suites Hotel Buckhead, Atlanta, GA, May 20-21, 1998 (invited for presentation by NIH).

Characterization and formulation of recombinant proteins, presentation followed by consulting for Procter & Gamble Co., Cincinnati, Ohio, May 5, 1998.

Formulation & Delivery of Therapeutic Peptides and Proteins, presentation given to Eli Lilly & Co. World Headquarters, Indianapolis, IN, November 21, 1997.

Organized (as one of the speakers) a 3-day, 3-speaker seminar on "Peptides and Proteins as Parenteral Dosage Forms: Practical Issues in Formulation", Hotel International, Basel, Switzerland, May 21-23, 1997.

Electrically enhanced transdermal delivery of drugs, presentation given to Empi, Inc., St. Paul, Minnesota, February 17, 1997.



Formulation development of peptide drugs, presentation given to Demeter Biotechnologies, Ltd., Durham, NC, October 24, 1996 (Host: Vice President, Product Development).

Organized and conducted (as one of the speakers) a 2-day, 2-speaker seminar on "Iontophoretic Transdermal Drug Delivery: A New Commercially Feasible Technology", Hotel International, Basel, Switzerland, October 17-18, 1996.

Electrically enhanced transdermal delivery of drugs, presentation given to Apollon, Inc., Malvern, Pennsylvania, October 11, 1996.

Formulation and Delivery of Therapeutic Peptides and Proteins, presentation given to Eurand America, Inc., a division of American Home Products, Dayton, Ohio, September 17, 1996.

Organized and conducted (as one of the speakers) a 2-day, 2-speaker seminar on "Therapeutic Peptides and Proteins: Practical Issues in Formulation Development", Hotel International, Basel, Switzerland, April 11-12, 1996.

Formulation of Therapeutic Proteins, Pharmaceutical Development, Ciba-Geigy World Headquarters, Basel, Switzerland, April 10, 1996 (Host: Dr. Tudor Arvinte, Head of Exploratory Formulation Development Laboratory).

Formulation and Delivery of Therapeutic Peptides and Proteins, Department of Pharmacy, King's College London, University of London, London, December 11, 1995 (Host: Dr. Gary P. Martin, Reader in Pharmaceutics).

Organized and conducted (as one of the speakers) a 2-day, 2-speaker seminar on "Therapeutic Peptides and Proteins: Practical Issues in Formulation Development", Sheraton Harbor Island Resort, September 28-29, 1995, San Diego, CA.

Transdermal iontophoretic delivery of drugs, Genetronics Inc., San Diego, CA, September 27, 1995, (Host: Dr. Gunter Hofmann, Founder, Chairman, and Chief Scientific Officer).

Conducted a Workshop on "Pharmaceutical Issues of Biotechnology Drugs" for the faculty of St. John's University, March 16, 1994, New York (Host: Faculty Development Committee).

Formulation and delivery of peptide/protein drugs, Ranbaxy Laboratories Ltd., New Delhi, India, January 3, 1994 (Host: General Manager-Pharma R&D).

Symposium speaker on "Formulation and delivery of peptide/protein drugs" at the 45th Indian Pharmaceutical Congress, Indian Institute of Technology, New Delhi, India, December 24, 1993 (Host: Scientific Services Committee).

Product Development of Peptide/Protein drugs, Pharma Development, R&D, Hoechst World Headquarters, Frankfurt, Germany, December 13, 1993 (Host: Head of Pharma Galenik).

Transdermal iontophoretic delivery of peptide/protein drugs, Institut für Pharmazeutische Technologie, der Johann Wolfgang Goethe-Universität, Frankfurt, Germany, December 13, 1993 (Host: Dr. J. Kreuter, Professor and Department Head).

Drug delivery systems for macromolecules, conference on "Improving the drug development process", Princeton, NJ, Sept.15-16, 1992 (Host: Institute for International Research, Pharmaceutical Division).

## TEACHING ACTIVITIES

### **Courses Taught/Mercer University**

*Professional/Undergraduate Level:* Pharmaceutics 326 (every Spring since 1999)

*Graduate Level:* Team taught Biotechnology 807 (every alternate Spring since 1999) and Drug Delivery Systems 839 (every alternate Summer since 1999). Also, coordinated Graduate Seminar 897 (1999-2000).

### **Courses Taught/Auburn University**

*Professional/Undergraduate Level:* *Pharmaceutical Biotechnology*: Course-Coordinator for this new course, offered first time in Fall 1998. Coordinated and taught one-third of the course; *Pharmaceutics II* (PY 302): Taught Spring 1992, 1993, 1994, 1995 and 1996; Winter 1998; covers physical pharmacy, disperse systems, parenterals, admixtures, transdermal, and aerosols; *Pharmaceutics IV* (PY 403): Introduced new topics (see new courses developed) in this course, which constitute one-fourth of the course; taught Spring 1993, 1994, 1995, 1996 and 1997; *Pharmaceutics IV Laboratory*: Introduced a laboratory on intravenous admixtures; taught Spring 1994, 1995 and 1996; *Bionucleonics* (PY537): Contribute laboratory to this course showing application of radioisotopes to drug delivery experiments; taught in Summer of 1994, 1995, 1996, 1997 and 1998.

*Graduate Level:* Appointed to Graduate Faculty, 6/94; Product Development (PY 603): Fall 1992; 1994; 1996 One third of a team taught course; parenterals (including laboratory); Formulation & Delivery of Peptide/Protein Drugs (PY 606): Fall 1993; Fall 1995; Winter 1997; Fall 1998.

*New Courses Developed:* *Formulation & Delivery of Peptide/Protein Drugs* - developed as a new 5 hour elective graduate course, which has also been approved as an elective for the inter-departmental minor in Biochemistry/Cell & Molecular Biology; Introduced two new topics to Pharmaceutics IV - "*Intravenous Admixtures*", and "*Fundamentals of Biotechnology and Pharmaceutics of Biotechnology-derived Peptide/Protein Drugs*"; Introduced a new laboratory session on "*Intravenous Admixtures*" in Pharmaceutics IV laboratory.

### **Researchers**

Dr. Chandrasekhar Kolli, Post doctoral scholar, 2004 - Present.

Dr. Zhaowei "Bruce" Jin, Post doctoral scholar, 2004.

Dr. Nikolay A. Patrushev, Post doctoral research associate, 2001-02.

Dr. Ye Yang, Post doctoral research scholar, 2004 - Present.

Dr. Paulos G. Yohannes, Sabbatical Researcher, 2002-03.  
(Professor of Chemistry, Georgia Perimeter College)

### **Graduate students**

#### **Major advisor/Current Ph.D. Students**

Parvin Akther  
Aniket Badkar  
Nishil Desai  
Purna Kasha  
Sahitya Katikaneni  
Sameer Late  
Guohua Li  
Jyotsna Paturi  
Pravada Pendse  
Srujana Siddoju  
Viswatej Vemulapalli

#### **Students Graduated**

Rashmi Upasani, Ph.D., Fall 2005 (Dissertation Title: Response surface modeling to evaluate active energy assisted skin transport technologies).

Ayyappa Chaturvedula, Ph.D., Spring 2005 (Dissertation Title: Pharmacokinetic evaluation of skin transport technologies).

Dipty Joshi, Ph.D., Summer 2004 (Dissertation Title: *Transdermal delivery of recombinant human insulin via micropores*)

Advait Badkar, Ph.D., Summer 2002 (Dissertation Title: *Transdermal delivery of interferon alpha 2b*)

Rajkumar V. Conjeevaram, Ph.D., Summer 2002 (Dissertation Title: *Electrically modulated transdermal delivery of beta blockers*)

Shu-Lun Chang (Cynthia), Ph.D., Spring 2000 (Dissertation Title: *Stability study of salmon calcitonin formulation and electrically assisted transdermal delivery of calcium regulating hormones and prostaglandin E1*)

Advait Badkar, M.S., Summer 1998 (Thesis Title: *Electrically enhanced transdermal delivery of a macromolecule*)

Shu-Lun Chang (Cynthia), M.S., Summer 1996 (Thesis Title: *Enhancement of percutaneous absorption of hydrocortisone*)

Manohar Katakam, Ph.D., Spring 1996 (Dissertation Title: *Use of Non-ionic Surfactants to Stabilize Recombinant Human Growth Hormone and to Develop its Sustained Release Formulation*)

Ruchira Mitra, M.S., Spring 1994 (Thesis Title: *Investigation of factors affecting transdermal iontophoretic delivery using model compounds*)

Manohar Katakam, M.S., Fall 1993 (Thesis Title: *Aggregation of protein drugs and its prevention by carbohydrate excipient*)

#### Co-Major Advisor

Raj Kumar Conjeevaram, M.S., Fall 1998 (Thesis Title: *Electrically-assisted in vitro delivery of propranolol HCl through human skin*)

Sagarika Bose, M.S., Summer 1998 (Thesis Title: *Electrically-assisted transdermal delivery of buprenorphine*)

Narendra Vutla, M.S., Fall 1996 (Thesis Title: *Liposomal formulation and transdermal iontophoretic delivery of the opioid peptide leucine enkephalin*)

#### Committee Member

Wijaya Martanto, Ph.D., Fall 2005 (Dissertation Title: Microinjection into skin using microneedles) (External member; Wijaya was student at Georgia Institute of Technology).

Dinesh Haswani, Ph.D., Fall 2005 (Dissertation Title: Evaluation of microencapsulated gentamicin on *E.Coli* in Gram negative sepsis).

Henry Nettey, Ph.D., Fall 2004 (Dissertation Title: The evaluation of vancomycin microspheres in *S.aureus* induced sepsis).

Mary Sou, Ph.D., Spring 2004 (Dissertation Title: The effect of chitosans and other excipients on the permeation of ketotifen and other drug models through Caco-2 cells).

Zhaowei Jin, Ph.D., Spring 2004 (Dissertation Title: Microsphere formulation strategies, cell uptake studies, and pharmacokinetics in rats)

Deepali A. Damle, Ph.D., Fall 2003 (Dissertation Title: *Oral proliposomal delivery of cromolyn sodium and tiludronate: Formulation and in vitro characterization in caco-2 cells and isolated rat gut*)

Arun K. Katragadda, Ph.D., Fall 2003 (Dissertation Title: *Effect of poly(acrylate) polymers and chitosan-inhibitor conjugates on the enzymatic degradation of a model peptide desmopressin and enhancement of its transport across caco-2 monolayers and rat intestinal segments*)

Rakesh Nagilla, Ph.D., Fall 2003 (Dissertation Title: Stereospecific pharmacokinetics of ketorolac in large animal species: Evaluation of an implantable delivery system in dogs)

Michael D. Green, Ph.D., Spring 2003 (Dissertation Title: *Preparation, characterization, and in vivo evaluation of albumin-encapsulated primaquine diphosphate*)

Robert H. Marion, Ph.D., Spring 2003 (Dissertation Title: *Determination of the applicability and validity of non-isothermal kinetic methods for use in pharmaceutical stability tests*)

Wenkai Tong, Ph.D., Summer 2001 (Dissertation Title: *Evaluation of camptothecin microspheres in cancer therapy*)

Tonia R. Burk\*, Ph.D., Spring 2001 (Dissertation Title: *Surface characterization and interactions in a dry powder inhalant drug delivery system*) [\* external member, Tonia was a graduate student in the Department of Chemical Engineering, Auburn University, Auburn, AL].

Rajesh Kumar, Ph.D., Fall 1999 (Dissertation Title: Thermodynamic study of antibiotics and development of novel delivery systems for poorly water soluble drug)

Lin Zhang, M.S., Spring 1999 (Thesis Title: *A sustained release gel of Ceftriaxone: Formulation development and in vitro characterization*)

Ram Kasina\*, Ph.D., 1998 (Dissertation Title: *Preformulation and formulation studies for transdermal delivery of benazepril*) [\* external member; Ram was graduate student at Mercer University School of Pharmacy, Atlanta, GA].

Deepali Damle, M.S., Summer 1998 (Thesis Title: Oral controlled release bioadhesive formulation of didanosine)

Arun Kumar, M.S., Summer 1998 (Thesis Title: Liposomal encapsulation, characterization, ocular delivery and cellular uptake of stavudine)

Shirishkumar B. Kulkarni, Ph.D., Spring 1997 (Dissertation Title: *Liposomal formulation, in-vitro characterization, delivery and cellular studies of colchicine*)

Joel S. Owen, Ph.D., Fall 1996 (Dissertation Title: "Applications of population pharmacokinetic analysis")

Satish Dipali, Ph.D., Fall 1996 (Dissertation Title: *In vitro and in vivo evaluation of long circulating liposomes encapsulating 2',3'-dideoxyinosine*)

Bhas Dani, M.S., Summer 1996 (Thesis Title: *Metabolism of [Des-Gly<sup>10</sup>, D-Trp<sup>6</sup>] LHRH ethylamide in rabbit nasal tissue: A comparison with cornea and conjunctiva*)

Evelyn Jane Ellis-Grosse, Ph.D., Spring 1996 (Dissertation Title: *The pharmacokinetics and pharmacodynamics of selected antiarrhythmic agents*)

Nima Akhavein, Ph.D. in progress

Dilip Devineni, Ph.D. in progress

Alphia Jones, Ph.D. in progress

Yin Lai, Ph.D. in progress

Naveen Bejugam, Ph.D. in progress

Aladin A. Siddig, Ph.D. in progress

Nasir Uddin, Ph.D. in progress

George Yeboah, Ph.D. in progress

## STUDENT RESEARCHERS

Adina Hirsch, AFPE Fellow, 2003-04

Valerie Michaud, Summer 2001, Mercer University, funded by Solvay Pharmaceuticals, GA.

## SERVICE ACTIVITIES

### National/State Committees

*Faculty Advisor*, Mercer University student chapter of American Association of Pharmaceutical Scientists (AAPS), 2003- present; *Chair*, Short Course Committee, Biotechnology Section, AAPS, 1999; Program Committee, Biotechnology Section, AAPS, 1999 and 1996; *Chair*, Education Committee,

Biotechnology Section, AAPS, 1996 and 1997; Membership Committee, Pharmaceuticals and Drug Delivery Section, AAPS, 1993-1995, and was *chair* of this committee for 1994 and 1995; Publicity Liaison Subcommittee, PDD Section, AAPS, 1995; Scholarship Committee, Alabama Academy of Science, Inc., 1993-95; Newsletter Committee, Alabama Academy of Science, Inc., 1993-96.

### University Committees

*Mercer University:* Graduate Council, 2004 - Present.  
Institutional Animal Care & Use Committee, 1999 - 2004.  
Institutional Radiation Safety Committee, 2002 - 03.  
Research Policies and Procedures Task Force, 2003

*Auburn University:* Graduate Council, 1998-99; Biogrants Committee, 1996-98; Membership Committee, 1995-96, Sigma Xi, The Scientific Research Society, Auburn University Chapter 106, Auburn University; Appointed (7/93) as participating *faculty* on the university wide inter-departmental minor in Biochemistry/Cell & Molecular Biology; Appointed (10/94) on the Steering Committee of the inter-departmental minor in Biochemistry/Cell & Molecular Biology.

### School Committees/Other Service Activity

#### *Mercer University, Atlanta, GA*

Search Committee for Director, Center for Clinical Research	2004-2005
<i>Chair</i> , Pharmaceuticals Search Committee	2003-2004
<i>Chair</i> , Research Award Recipient Selection Ad hoc Committee	2002-2004
Curriculum Committee	2003-2004
Resources & Facilities Subcommittee, Graduate Program Self Study	2002-2003
<i>Chair</i> , Distinguished Research Award Criteria Ad hoc committee	2001-2002
Web Page Sub-Committee, Centennial Celebrations	2000-2003
Publicity Sub-Committee, Centennial Celebrations	2000-2003
Assessment Self-Study Committee	2000-2002
Institutional Assessment Committee	2000-2003
Academic Performance and Standards Committee	1999-2002
Non-Academic Disciplinary Committee	1999-2000
<i>Chair</i> , Non-Academic Disciplinary Committee	2002-2004
Admissions Interview Team	1999-2000
Distinguished Educator Award Committee	1999-2000

#### *Auburn University, Auburn AL*

Admissions and Academic Standards Committee 1996-1998; Medical Resources Committee 1996-1998; Building Renovation Committee 1998; *Chair*, Computing Services Committee 1993-1996; Computing Services Committee 1992-1996; Mentor to Students Team for Pharmacy Practice Experiences 1997-1999.

### Department Committees, Auburn University

Search Committee, Pharmaceuticals 1998; *Chair*, Ad-hoc Committee to formulate course 1996 content for new Pharmaceutical Biotechnology course 1996; B.S. in Pharmaceutical Sciences 1991-92

### Continuing Education

Continuing Education Presentation/Program

Parenteral Certification Program, School of Pharmacy, Auburn University, February 25, 1996, April 21, 1996, February 23, 1997, August 15, 1997, March 15, 1998, March 19, 2000, May 18, 2003, May 15, 2004, and May 14, 2005 - 5.0 hour (each time) Certification program with hands-on laboratory required by State Board for pharmacists working with parenterals; Delivery systems for biotechnology drugs, Fall 1993 C.E. Program at School of Pharmacy, Auburn University; Transdermal Drug Delivery, Fall 1992 C.E. Program at School of Pharmacy, Auburn University.

Continuing Education Articles

Articles in *US Pharmacist*, *Pharmacy Times*, and *J. Practical Nursing*; see publications list.

Peer Review Activities

Invited Book Reviews:

Reviewed a book chapter for an upcoming ACS Symposium Series Book, Polymeric drug delivery: Science and applications, October 2004.

Reviewed a book proposal for Kluwer Academic Publishers, New York, 7/02 and for CRC Press, 8/02 & 1/04.

Pharmaceutical Biotechnology: Fundamentals and essentials, Eds Melvin E. Klegerman and Michael J. Groves, Interpharm Press, Inc., 1992, for *BioPharm*, Vol.6, No.8, October 1993, p.57.

Pharmaceutical Dosage Forms and Drug Delivery Systems, Howard C. Ansel, Nicholas G. Popovich and Loyd V. Allen, Williams & Wilkins, 1995, reviewed for publisher to prepare next edition.

Pharmaceutical Dosage Forms and Drug Delivery Systems, Howard C. Ansel, Nicholas G. Popovich and Loyd V. Allen, Lippincott Williams & Wilkins, 1999, reviewed for publisher to prepare next edition.

Reviewed a book proposal for Taylor & Francis Ltd., London, UK, 10/98.

Journal Reviewer:

American Journal of Drug Delivery  
 Archives of Physical Medicine and Rehabilitation  
 Bioelectrochemistry and Bioenergetics  
 BIODRUGS  
 Critical Reviews in Therapeutic Drug Carrier Systems  
 Drug Development and Industrial Pharmacy  
 European Journal of Pharmaceutical Sciences  
 Experimental Biology and Medicine  
 International Journal of Cancer  
 International Journal of Pharmaceutics  
 International Journal of Pharmaceutical Compounding  
 Investigative Ophthalmology and Visual Science  
 Journal of Controlled Release  
 Journal of Drug Targeting  
 Journal of Nanoscience & Nanotechnology  
 Journal of Pharmaceutical Sciences  
 Journal of Pharmaceutical and Biomedical analysis  
 Journal of Pharmacy and Pharmacology  
 Journal of Pharmacy Teaching  
 Pharmaceutical Development & Technology  
 Pharmaceutical Research  
 PharmSci, a journal of American Association of Pharmaceutical Scientists  
 PharmSciTech, a journal of American Association of Pharmaceutical Scientists  
 Physiotherapy Research International  
 Research Communications in Chemical Pathology & Pharmacology  
 Vaccine

Abstract Screening:

Joint PDD-BIOTEC Session, AAPS, 1996  
 Pharmaceutics and Drug Delivery Section (PDD), AAPS, 1995  
 BIOTEC Section, AAPS, 1998  
 Pharmaceutics Section, AACP, 1999  
 Dermal Absorption/Transport/Topical Areas, AAPS, 1999

Grant Reviews

Reviewed NIH grant proposals for Florida A&M University for their Minority  
 Biomedical Research Support Program, April 2000 and March 2004.

Reviewer for the Mercer-Solvay Summer Research Program Grants, March 2000 and  
 April 2002.

Member of the 1998-99 Pharmaceutics Review Panel for New Investigators Program for  
 Pharmacy Faculty, American Association of Colleges of Pharmacy (AACP).

Other: External reviewer for Promotion & Tenure Committees at St. John's University  
 (2004 and 2001), Western University (2002), and Campbell University (2003). Served as



a judge for the May, 1992 Graduate Research Forum for Scientific Presentations in the Sciences Category, Auburn University, AL.

**PROFESSIONAL AFFILIATION**

American Association of Pharmaceutical Scientists; American Association of Colleges of Pharmacy; Controlled Release Society, Inc.; Society of Cosmetic Chemists; Rho Chi; Kappa Psi; Sigma Xi

*- Revised January 2006.*